(b) proteins or polypeptides capable of binding polyethylene glycol, and wherein said protein or polypeptide is not encapsulated in said colloidal particles.

Please add new claims 20 and 21 as follow:

--20. The pharmaceutical composition of Claim 1 wherein said colloidal particles further comprise a second amphipathic lipid obtained from either natural or synthetic sources.--

--21. The pharmaceutical composition of Claim 20 wherein said second amphipathic lipid is phosphatidylcholine.--

REMARKS

Claims 1-21 are currently pending. By the Office Action, claims 1-19 are subject to Restriction. By this Preliminary Amendment, claims 5 and 18 are amended, and claims 20 and 21 are added. No new matter is added.

The attached Appendix includes marked-up copies of each rewritten claim (37 C.F.R. §1.121(c)(1)(ii)).

Restriction Requirement

In reply to the Restriction Requirement mailed March 27, 2002, Applicants provisionally elect Group I, claims 1-13, with traverse.

Applicants assert that claims 1-19 share the same special technical feature, linking the inventions of Groups I-V, that defines a contribution over the prior art. Specifically, claims 1-19 share the following special technical feature: a therapeutically effective amount of a protein or polypeptide and substantially neutral colloidal particles, wherein the protein is not encapsulated in the colloidal particles.

The Office Action indicates that Woodle discloses that a protein may be coupled to the surface of a liposome, and cites column 12, lines 4-68. However, Applicants submit that

this does not teach the special technical feature of claims 1-19. Specifically, Woodle does not teach that the therapeutic protein is not encapsulated by the liposome. Instead, at column 12, line 54-column 13, line 3, Woodle discloses encapsulating a chemotherapeutic agent within a liposome, and attaching a ligand such as an antibody to the surface of the liposome to target the liposome-encapsulated chemotherapeutic agent to the diseased cell. However, Woodle does not teach or suggest that the chemotherapeutic agent is not encapsulated with the liposome. In addition, Woodle teaches away from the invention claimed in claims 1-19 by requiring that the therapeutic agent be encapsulated in the liposome. For at least these reasons, Applicants submit that Woodle does not teach or suggest the special technical feature of claims 1-19 of the present invention.

Reconsideration and withdrawal of the Restriction Requirement are respectfully requested in light of the special technical feature that claims 1-19 of the present invention share that defines a contribution over a prior art.

Thus, withdrawal of the Restriction Requirement is respectfully requested.

Claim Amendments/Additions

Claim 5 has been amended to correct a typographical error. This amendment is not a narrowing amendment, and is not for the purpose of patentability. Support for claim 5 can be found at least on page 5, lines 10-12, of the present specification.

Claim 18 has been amended to correct a typographical error. This amendment is not a narrowing amendment, and is not for the purpose of patentability.

Support for new claims 20 and 21 can be found on page 8, lines 16-26, of the present specification.

Claims 20 and 21, which ultimately depend from claim 1 and thus include all of the limitations of claim 1, including the special technical feature, should be examined with claim 1 and thus Group I.

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-21 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

James A. Oliff
Registration No. 27,075

Philip A. Caramanica
Registration No. P-51,528

JAO:PAC/jca

Attachment:
Appendix

Date: June 27, 2002

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry;
Charge any fee due to our Deposit Account No. 15-0461

APPENDIX

Claims 20 and 21 are added.

The following are marked-up versions of the amended claims:

5. (Amended) The pharmaceutical composition of Claim 4 wherein said amphipathic lipid is ~~egg phosphatidylcholine~~ phosphatidylethanolamine (PE).

18. (Amended) A pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge,

wherein said protein or polypeptide is selected from the group consisting of:

(a) proteins or polypeptides capable of externally binding said colloidal particles; and

(b) proteins ~~of~~ or polypeptides capable of binding polyethylene glycol,

and wherein said protein or polypeptide is not encapsulated in said colloidal particles.